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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,933	06/07/2001	Jeff Gray	014907001910	1440

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/877,933	GRAY ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☒ Claim(s) *16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed September 17, 2004 has been entered. The examiner acknowledges the amendments to the specification. Claims 2-3 and 16 have been amended. Claims 7 and 17-31 have been cancelled. Claims 1-16 are under consideration.

Withdrawal of Rejections

2. The following rejections have been withdrawn in view of applicants' amendments, declaration and arguments:

a) The written description rejection of claims 2,3 and 16 under 35 U.S.C. 112, first paragraph.
b) The rejection of claims 2-3 and 16 under 35 U.S.C. 112, second paragraph.
c) The rejection of claims 1,3-6 and 8-13 under 35 U.S.C. 103(a) as being unpatentable over Anusz et al., in view of Blunt et al.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 1-13 are drawn to a method of diagnosing infection of a mammal by an infection of a mammal by a *Cryptosporidum* species comprising contacting a stool sample with a capture reagent. Claims 14-16 were drawn to a kit comprising a solid support immobilized with a capture reagent. The written description in this case only sets forth antibodies and fails to disclose a broad class of capture reagents, therefore the written description is not commensurate in scope with the claims drawn to capture reagents. Neither the specification nor the claims teach how to define capture reagents. Neither the claims nor the specification teach how to obtain capture reagents that are not antibodies. The specification does not provide a clear protocol describing other capture reagents which had been isolated at the time the invention was made. There is no guidance as to what the capture reagents can be, other than antibodies. The specification does not provide structural characterization of the of said capture reagents. The specification appears to allege functionality as capable of binding to the protein disulfide isomerase, with no evidence structural evidence of the broad class of capture reagents supported by the instant specification. Nor is there guidance as to what capture reagents, other than antibodies, which can or cannot be used in the method and kit being claimed. The specification does not include structural examples of capture reagents. Thus, the resulting capture reagent could result in a complexes not taught and enabled by the specification.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named antibodies, the skilled artisan cannot envision the detailed structure of the capture reagents, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus.

In view of the lack of evidence in the specification as filed, it is apparent that one skilled in the art would recognize that applicants were not in possession, at the time of filing the instant application, of the broad class of capture reagents. Absent characterization of the claimed capture reagents, the genus of capture reagents is highly diverse and applicants have failed to describe such capture reagents. In view of

these considerations, a person of skill in the art would not have viewed the teachings of the specification sufficient to show that Applicants were in possession of capture reagents as asserted in the specification and claims. Therefore only the recited antibodies and not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 14-15 are rejected under 35 U.S.C. 102(e) as being anticipated by of Braxton et al., US Patent 5,798,249. Claims 14-15 are drawn to kit for diagnosing infection of a mammal by a *Cryptosporidum* species comprising a solid support, a detection reagent, and positive control.

Braxton et al., teach novel human protein disulfide isomerases (PDI). The invention provides for diagnostic kits for the detection of PDI (col. 5 lines 7-8). It provides for the use of purified PDI as a positive control and to produce antibodies that can be used to quantitate the amount of PDI (col. 5 lines 8-11). A variety of protocols for detecting and measuring PDI are known in the art. They can use polyclonal or monoclonal antibodies in ELISA assays and radioimmunoassays (col. 5 lines 30-32).

ELISA's generally require a solid support with a capture reagent immobilized thereon. Braxton et al., teach antibody capture reagents. Braxton et al., teaches a two-site monoclonal based immunoassay using monoclonal antibodies reactive to two non-interfering epitopes on PDI (col. 5 lines 32-35). Suitable reporter molecules or labels include enzymes, fluorescent, chemiluminscent or chromatographic agents that are all commercially available (col. 5 lines 52-57). The PDI antibodies are useful for the diagnosis of conditions and diseases associated with the expression of PDI (col. 18 lines 65-66). These immunoassays typically involve the formation of complexes between PDI and its specific antibody and the measurement of complex formations (col. 19 lines 1-6). Frequently, the polypeptide and antibodies will be labeled by joining them with a reporter molecule (col. 19 lines 19-24).

Therefore, Braxton et al., teach the detection kit comprising a solid support, a capture reagent, a detection reagent, and positive control and the convenience to the consumer wherein the assembly of an immunoassay reagent kit is routine in the art.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
November 24, 2004

PATRICIA A. DUFFY
PRIMARY EXAMINER